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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/444,790	05/19/1995	MANFRED BROCKHAUS	9189	5612
151	7590	10/21/2003	EXAMINER	
HOFFMANN-LA ROCHE INC. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110			MURPHY, JOSEPH F	
		ART UNIT	PAPER NUMBER	
		1646	H/	
DATE MAILED: 10/21/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application N .	Applicant(s)
	08/444,790	BROCKHAUS ET AL.
	Examiner	Art Unit
	Joseph F Murphy	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 31 July 2003.

2a) This action is **FINAL**.                                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 62-99 is/are pending in the application.

4a) Of the above claim(s) 78-99 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 62-77 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Formal Matters***

The supplemental amendment of Paper No. 38, 8/16/2002 crossed in the mail with the Office action of Paper No. 37, 8/21/2002. Claims 78-99 were added in Paper No. 38, 8/16/2002. Claims 62-99 are pending. Newly submitted claims 78-99 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the DNA of claims 78-99 and the receptor protein of claims 62-77 are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function, and each has an independent use, that is distinct for each invention which cannot be exchanged. In the instant case, nucleic acids and proteins are distinct because their structures and modes of action are different, which require non-coextensive searches, and furthermore, the DNA of claims 78-99 can be used as a hybridization probe, while the protein of claims 62-77 can be used for the production of antibodies or screening of compounds.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 78-99 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 62-77 are under consideration.

### ***Response to Arguments***

Applicant's arguments filed in Paper No. 40, 7/31/2003 have been fully considered but they are not persuasive for the reasons set forth below.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 62-77 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,981,701 (Wallach et al.), for reasons of record set forth in Paper No. 32, 4/17/2002, and as evidenced by U.S. Patent No. 5,811,261 (Wallach et al.). U.S. Patent No. 5,981,701 has a priority date of 9/12/1988.

The rejection of record set forth that Wallach discloses purification of a tumor necrosis factor inhibitory protein, which interacts with TNF and inhibits the binding of TNF to its receptors and the cytotoxic effects of TNF (column 3 line 65 to column 4 line 4). The protein disclosed in Wallach has a molecular weight of 40-80 kD (column 16 line 44), and comprises an amino acid sequence that is identical to the sequence of the protein claimed in the instant application (column 16, line 56), thus claims 62-66, 69, 72, 75 are anticipated. Wallach further sets forth the methods to produce the TNF inhibitor protein recombinantly from host cells (column 12, line 11-column 15, line 53), thus anticipating claims 67-68, 70-71, 73-74, 76-77.

Applicant argues that the '701 patent discloses a different protein than that claimed in the instant claims. Applicant argues that the protein of the '701 patent has a different N-terminus amino acid sequence compared to the instantly claimed protein. Applicant also argues that the '701 patent does not disclose the instantly claimed receptor protein. Applicant further argues

that the '701 patent does not disclose a protein of molecular weight 40-80 kD. However, the '701 patent discloses a protein which is between 40-80 kD, thus meeting the limitation of "about 55 kD". The protein of the '701 patent is 100% identical to the amino acid sequence as set forth in Figure 1 of the instant application, as evidenced by the sequence as set forth in the '261 patent, see SEQ ID NO: 2. In the '701 patent, claim 2 is directed to a purified protein which contains the sequence, but that sequence is not claimed as being the N-terminal end of the protein, only that the protein must "contain" the sequence. Thus, the protein set forth in the '701 patent inherently possess the sequence of SEQ ID NO: 2 of the '261 patent even though the full sequence was not set forth until the '261 patent. They are the same protein. Thus, claims 62-66, 69, 72, 75 are anticipated. The methods to produce the TNF inhibitor protein recombinantly from host cells are disclosed in the Wallach patent (column 12, line 11-column 15, line 53), thus anticipating claims 67-68, 70-71, 73-74, 76-77.

Claims 62-77 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,811,261 (Wallach et al.), for reasons of record set forth in paper No. 37, 8/21/2002. U.S. patent No. 5,811,261 has a priority date of

The '261 patent discloses purification of a tumor necrosis factor inhibitory protein, which interacts with TNF and inhibits the binding of TNF to its receptors and the cytotoxic effects of TNF (column 2 lines 1-3). The protein disclosed in the '261 patent has a molecular weight of 40-80 kD (column 9 lines 34-35). the full amino acid sequence of the TNF inhibitory protein of Wallach is set forth in the '261 patent (see SEQ ID NO: 2). The sequence of SEQ ID NO: 2 of the '261 patent is 100% identical to the amino acid sequence of the protein claimed in the instant application, and is 100% identical from amino acids 1-180 of the protein claimed in the instant application. Thus, claims 62-66, 69, 72, 75 are anticipated. The methods to produce the TNF inhibitor protein recombinantly from host cells are disclosed in the Wallach patent (column 12, line 11-column 15, line 53), thus anticipating claims 67-68, 70-71, 73-74, 76-77.

Applicant argues that the '261 patent is not prior art for the purposes of 102(e) since the sequence of the protein was new matter added to the 07/625,668. However, tumor necrosis factor inhibitory protein was disclosed in the parent application 07/243,092, as well as the partial sequence, which demonstrates that this is the same protein as claimed in the instant application with the amino acid sequence as set forth in SEQ ID NO: 2. Since the amino acid sequence of the protein is inherent, and the 07/243,092 application set forth both the size of the protein, and a partial sequence which demonstrates that it is the same protein, the '261 patent is qualified as prior art under 102(e).

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
October 15, 2003



YVONNE EYLER, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600